

**§ 121.10 Responsibilities of the responsible official.**

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biosafety and Security Plan in accordance with § 121.12;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 121.3 in accordance with § 121.11;

(3) Providing appropriate training in biosafety, containment, and security procedures for all personnel in accordance with § 121.13;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 121.14;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS or, for overlap agents or toxins, APHIS or CDC, of changes in circumstances in accordance with § 121.7;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 121.17;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 121.3 in accordance with § 121.15.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entities possessing, using, or transferring agents or toxins listed in § 121.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.<sup>10</sup> During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

(c) In addition to the requirements in paragraph (a) of this section, the responsible official must ensure that the following experiments are not conducted unless approved by the Admin-

istrator, after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a pathogenic trait or drug resistance trait to biological agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD<sub>50</sub><100 ng/kg body weight.

**§ 121.11 Restricting access to biological agents and toxins.**

(a) An individual may not have access to biological agents or toxins listed in § 121.3 unless approved by APHIS or CDC. APHIS will grant, limit, or deny access of individuals to listed agents or toxins. APHIS or CDC will grant, limit, or deny access of individuals to overlap agents or toxins.

(b) The responsible official is responsible for ensuring that only approved individuals within the entity have access to any agents or toxins listed in § 121.3. The responsible official must request such access for only those individuals who have a legitimate need to handle or use agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

(c) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(d) For each individual identified by the responsible official as having a legitimate need to handle or use agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General. For overlap agents or toxins, the responsible official must submit this information to either APHIS or CDC and the Attorney General.

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS or, for overlap agents or toxins, APHIS or CDC (*e.g.*, curriculum vitae

<sup>10</sup>A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734-3652.